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| APPLICATION NO.         | FILING DATE        | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |  |  |
|-------------------------|--------------------|----------------------|---------------------|------------------|--|--|
| 10/614,176              | 07/08/2003         | Taik Koo Yun         | 0662-0189P          | 6452             |  |  |
| 2292                    | 7590 03/29/2005    | ,                    | EXAM                | EXAMINER         |  |  |
| BIRCH STE<br>PO BOX 747 | WART KOLASCH &     | COE, SU              | COE, SUSAN D        |                  |  |  |
|                         | RCH, VA 22040-0747 |                      | ART UNIT            | PAPER NUMBER     |  |  |
|                         |                    | •                    | 1654                |                  |  |  |

DATE MAILED: 03/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| <del></del>   |  | Application No.     | <del></del>           | Applicant(s)           |        |  |  |  |
|---|--|---------------------|-----------------------|------------------------|--------|--|--|--|
| Office Action Summary   |  |                     | '                     |                        |        |  |  |  |
|   |  | 10/614,176          |                       | YUN ET AL.             |        |  |  |  |
|   |  | Examiner            |                       | Art Unit               |        |  |  |  |
|   |  | Susan D. Coe        | n chook with the o    | 1654                   | Idroop |  |  |  |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply  |  |                     |                       |                        |        |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). |  |                     |                       |                        |        |  |  |  |
| Status  |  |                     |                       |                        |        |  |  |  |
| 1)[🛛  | Responsive to communication(s) filed on 12   | January 2005.       |                       |                        |        |  |  |  |
| •   | This action is <b>FINAL</b> . 2b) This action is non-final.  |                     |                       |                        |        |  |  |  |
| · · · · · · · · · · · · · · · · · · ·   | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is                  |                     |                       |                        |        |  |  |  |
|   | closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.  |                     |                       |                        |        |  |  |  |
| Disposition of Claims   |  |                     |                       |                        |        |  |  |  |
| 4)⊠ Claim(s) <u>1 and 3-7</u> is/are pending in the application.  |  |                     |                       |                        |        |  |  |  |
| -   | 4a) Of the above claim(s) is/are withdrawn from consideration.   |                     |                       |                        |        |  |  |  |
| 5) Claim(s) is/are allowed.   |  |                     |                       |                        |        |  |  |  |
| 6)⊠   | 6)⊠ Claim(s) <u>1 and 3-7</u> is/are rejected.   |                     |                       |                        |        |  |  |  |
| 7)  | 7) Claim(s) is/are objected to.  |                     |                       |                        |        |  |  |  |
| 8)[   | Claim(s) are subject to restriction and  | or election require | ement.                |                        |        |  |  |  |
| Applicati   | on Papers  |                     |                       |                        |        |  |  |  |
| 9)□ '   | The specification is objected to by the Exami  | ner.                |                       |                        |        |  |  |  |
| •   | The drawing(s) filed on is/are: a)☐ ad   |                     | jected to by the E    | Examiner.              |        |  |  |  |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).   |  |                     |                       |                        |        |  |  |  |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  |  |                     |                       |                        |        |  |  |  |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.  |  |                     |                       |                        |        |  |  |  |
| Priority under 35 U.S.C. § 119  |  |                     |                       |                        |        |  |  |  |
| <ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No.</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>  |  |                     |                       |                        |        |  |  |  |
| Attachment(s)   |  |                     |                       |                        |        |  |  |  |
| 1) Notice of References Cited (PTO-892)  4) Interview Summary (PTO-413)  Paper No(s)/Mail Date  |  |                     |                       |                        |        |  |  |  |
| 3) Inform   | e of Draftsperson's Patent Drawing Review (PTO-948)<br>nation Disclosure Statement(s) (PTO-1449 or PTO/SB/0<br>r No(s)/Mail Date |                     | Notice of Informal Po | atent Application (PT0 | O-152) |  |  |  |

Application/Control Number: 10/614,176 Page 2

Art Unit: 1654

## **DETAILED ACTION**

1. The amendment filed January 12, 2005, has been received and entered. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior Office action.

- 2. Claims 2 and 8-10 have been cancelled.
- 3. Claims 1 and 3-7 are pending.

# Claim Rejections - 35 USC § 102

4. Claims 1 and 3-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Yun et al. (Cancer Epidemiol. Biomarkers & Prev. (1995), vol. 4, pp. 401-408) for the reasons set forth in the previous Office action.

All of applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive. Applicant argues that Yun does not anticipate the claims because Yun does not teach reducing the occurrence of cancer using a composition comprising the claimed ginsenosides as the active ingredient. However, Yun is treating the same patient with the same composition. Ginseng naturally contains all of the ginsenosides claimed (as disclosed by applicant on pages 9 and 10 of the specification, these three ginsenosides are present in any ginseng, particularly in red ginseng). Therefore, Yun is reducing the occurrence of cancer with a composition that comprises the ginsenosides claimed. Thus, Yun meets every positive limitation of the claim, the same patient is administered the same composition for the same overall purpose. Therefore, the ginsenosides in the composition of Yun must be the active ingredient if applicant's invention functions as claimed.

Art Unit: 1654

Please note that Yun specifically teaches that ginseng is able to reduce the occurrence of lung cancer (see page 407, last paragraph). In addition, Yun teaches that the ginsengs contain amino acids (see page 407, first full paragraph); thus, the reference is considered to teach applicant's claim 6. Furthermore, Yun teaches that vitamins are also useful in reducing the occurrence of cancer (see page 406, first column, second full paragraph); thus, the reference is considered to teach using vitamins to reduce the occurrence of cancer in addition to the use of ginseng. Finally, Yun does not specifically mention the concentration of ginsenosides in the ginseng composition; however, Yun does teach that the amount of ginseng ingested by the patient can vary (see Table 3). The higher amounts of ginseng intake would contain the amount of ginsenosides claimed in applicant's claim 4.

## Claim Rejections - 35 USC § 103

5. Claims 1, 3, and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yun et al.

As discussed above, Yun does not specifically mention the concentration of ginsenosides in the ginseng composition; however, Yun does teach that the amount of ginseng ingested by the patient can vary (see Table 3). It seems very reasonable to assume that the higher amounts of ginseng intake would contain the amount of ginsenosides claimed in applicant's claim 4. However, even if the amounts specifically taught by Yun do not contain the requisite amount of ginsenosides, a person of ordinary skill in the art would be motivated to increase the amount of ginseng taken by the patient because the reference teaches that the risk of cancer decreases with

Art Unit: 1654

in a direct relationship with an increased amount of ginseng intake. This increase would yield intakes with the required amounts of ginsenosides.

#### 6. No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Coe whose telephone number is (571) 272-0963. The examiner can normally be reached on Monday to Thursday from 8:00 to 5:30 and on alternating Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can be reached on (571) 272-0974. The official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Art Unit: 1654

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding can be directed to the receptionist whose telephone number is (571) 272-1600.

Ama D. We 3-16-09

Susan D. Coe

Primary Examiner

Art Unit 1654